March 17, 1999

MEMORANDUM

SUBJECT: **RESPONSE TO AMVAC COMMENTS ON HED INTERIM RISK ASSESSMENT FOR DDVP - Bar Code: D255064**

FROM: David Jaquith
Chemical Exposure Branch 2
Health Effects Division (7509C)

TO: Sue Hummel, Senior Scientist
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Here are the replies to the comments provided by Amvac Chemical in response to HED's Preliminary Risk Assessment for Dichlorvos (DDVP). The statements of the risk assessment are included for clarity with the specific areas of concern redlined where appropriate.

47. **p. 39,#6,L2:**

The risk assessment states "Exposure estimates for crack and crevice treatment with DDVP were obtained from PHED (V1.1). It was assumed that a commercial applicator will treat 10 homes with DDVP in a day, which is probably a conservative assumption. The dermal dose was estimated to be 0.0094 mg/kg/day (MOE=53) and the inhalation dose was estimated to be 0.0091 mg/kg/day (MOE=55). The dermal, inhalation, and total MOEs are considered to be acceptable. All MOEs for crack and crevice treatment in homes (by certified pest control operators) are >10."

AMVAC Comments: "The revised technical label restricts the use of crack and crevice treatment to 5 homes/day rather than the 10 mentioned here. It is noted that a number of assumptions are made in this document that are contrary to the proposed revised label. Also it is difficult to comment on the correctness of many values employed as the relevant papers have not been made available. A separate note has been sent to the Agency on this matter (letter appended)."

Response: The registrant is correct. Both the latest accepted label (2) and the proposed label (3) contain the above restriction, limiting the number of homes that may be treated in a given day to 5. The applicator is restricted to making no more than once a week. The current product labels, however, do not reflect this restriction. The risk assessment was based on outdated information received verbally from the National Pest Control Association. If this restriction is included in the **product** labels The exposure/risk assessment for this scenario (4) used values from would be revised to include this information. The exposure values would then be reduced by 50 percent to 0.0095, yielding a MOE of 52.

48. **p40,#2,L4:**

The risk assessment states: "The inhalation exposures ranged from 0.0015 to 0.0045 mg/kg/day (MOEs of 11 to 33) and dermal exposures ranged from 0.0014 to 0.022 mg/kg/day (MOEs of 71 to 4.5), depending on application equipment (Jaquith 1998n). Dermal, inhalation, and total MOEs < 30 are considered to be of concern; specifically, the Agency has a risk concern for scenarios involving use of a backpack sprayer and a portable sprayer on a cart."

AMVAC Comments: "Amvac is unable to comment on the risk concerns highlighted by the Agency with respect to backpack sprayers and a portable sprayer on a cart as it has not been able to see details of the appropriate data."

Response: The supporting technical documents have been sent to Amvac after the receipt of these comments.

49. **p41,#2,L1:**

The risk assessment states: "The exposures after 10 hours were estimated to be 0.0023 mg/kg/day (MOE=210) via the dermal route and 0.000097 mg/kg/day (MOE=5100) by inhalation. Both inhalation and dermal MOEs are considered to be acceptable when re-entry occurs 10 hours after application of DDVP. The MOE for total exposure (with re-entry at 10 hours) is 208, which is considered to be acceptable."

AMVAC Comments: "It is not clear why a 10 hour period was chosen or where the data comes from"

Response: HED has no data addressing foliar dislodgeable residues of DDVP on greenhouse plants and was forced to use limited data from a turf study to extrapolate to the greenhouse scenario. Data in that study were collected at intervals of <2, 2, 6, 10, 24, 48, 72 and 96 hours. Treatment was assumed to occur at the end of a work day, making it unlikely that reentry would occur before 10 hours had elapsed. There were no data with which to conduct a reliable extrapolation between residues found at the 6 hour and 10 hour intervals. The supporting technical documents have been sent to Amvac after the receipt of these comments.

50. **p41,#3,L5:**

The risk assessment states: "Dairy barn application and direct application to cattle were used as the reference facility for these exposure assessments (Jaquith 1998l). There are no data addressing the use of DDVP in other types of animal facilities. Worker exposure from direct application to animals is based on dairy cattle treatment. A one percent solution of DDVP is applied with a handheld sprayer to an average herd of dairy cattle consisting of 65 head, each requiring 24 seconds to spray, two times per day during treatment. Applicators were assumed to wear long sleeve shirts, long pants, and gloves. Fly control is required from May to October with application occurring weekly during this time (26 times per year)..."

AMVAC Comments: "The proposed label limits applications to once a day."

Response: The registrant is correct in that both the latest accepted label (2) and the proposed label (3) contain the above restriction, limiting the number of times an animal can be treated to once a day. However, the existing product labels do not reflect this restriction. Some of the labels specify or recommend that the product be applied twice a day, morning and night (i.e. EPA Reg. Nos. 34704-578, 19713-354, 5481-200, 2217-450, 228-103). Values from a use report generated by BUD (now BEAD) were used for this assessment (5). At any rate this has no effect on the risk assessment. **The exposure values were based on the amount of material handled per day, not daily time or frequency of application.** Therefore the number of applications per day makes no difference, only the total amount applied to each animal per day.

p42,#3,L1:

The risk assessment states: "In estimating reentry exposure, EPA assumed 6 hours elapsed before reentry is allowed, as required on labels; and that workers spend 8 hours per day in the treated area for the next 3 days. Dichlorvos is applied at the rate of 2.0 grams active ingredient per 1,000 ft^3 over a period of 125 minutes per application. Exposure estimates are for the day following treatment. Dermal exposure was measured for the hands only and represents an average of the total exposure measured for three work stations. This exposure scenario was considered to be short term due to rapid dissipation of DDVP. Therefore, a NOEL of 0.5 mg/kg/day from the acute human study was used for the short term inhalation and dermal risk assessments and an 11% dermal absorption were used for dermal risk assessment. An MOE of 10 is required."

AMVAC Comments: The use rate of 2.0 g ai/1000 ft^3 requires a reentry interval of 24 hours not the 6 hrs mentioned here. There is also some inconsistency in the paragraph as line 4 talks about exposure estimates the day following treatment.

Response: The values for warehouse treatment were derived from a study submitted by AMVAC for treatment of food processing establishments (in this case, a cake mix factory)(6). The material was applied at a rate of **2.4 g ai per 1000 ft^3** using wall-mounted fogging units. The label restrictions for that study required that at least **6 hours** elapse before workers could enter the building. Examination of the **product** labels indicates that a number of these have either reentry intervals of 6 hours or the reentry interval is not specified (i.e. EPA Reg. Nos.47000-71, 47000-74, 44215-67, 65717-38, 6218-57, 5440-114, 769-797, 769-628). **While the technical label does specify a 24 hour reentry the product labels do not always include this language.** The risk assessment was based on the **product** label language and warehouses were considered to have the same exposure parameters as food preparation establishments.

p43,#2,L2

The risk assessment states: "The Agency estimated the risk to residents for different clothing scenarios. Pressurized aerosol products containing DDVP do not list any clothing requirements, therefore the Agency is assuming that DDVP is applied during hot weather when an individual will be wearing the least amount of clothing (i.e., shorts and shoes) with a dermal exposure of 0.0038 mg/kg/day (MOE = 132). Respiratory exposure was estimated to be approximately 79 ng/kg/day (MOE = 633). Inhalation, dermal, and total MOEs are considered to be acceptable."

AMVAC Comments: Homeowner use of pressurized aerosol products are no longer permitted under the proposed revised labels.

Response: The registrant is correct in that the technical label specifies that aerosol spray cans are ”For sale to, use and storage by licensed pest control operators only.”. However there are still labels that do not carry this restriction (i.e. EPA Reg. Nos. 706-72, 47000-62). If these labels are amended to prohibit non-commercial use of these products the residential exposure analysis becomes moot and can be removed from the risk assessment.

p43,#4,L2:

AMVAC Comments: Delete one of the “ofs”.

Response: Typographical error.

p43,#4,L9:

AMVAC Comments: Change “0.5" to “0.5 mg/kg/day”.

Response: Minor grammatical change.

p44,#2:

AMVAC Comments: Amvac strongly disagrees with the NOEL used in this calculation and hence the MOEs derived from the calculations.

Response: This is a technical issue that will be addressed at a future date.

p44,#3,L1:

The risk assessment states: "The assessment for flea collar exposure was derived from a study submitted by a previous registrant. There were a number of technical problems with that study and it is considered a weak data set (Jaquith 1987) . The inhalation NOEL of 0.05 mg/kg/day from a chronic rat study was used for inhalation risk assessment. An MOE of 300 is required. It was assumed that an individual spends 1 hour per day in close proximity to an animal wearing a flea collar and 8 hours per day in the general area (Jaquith 1998d). There are no data with which to estimate dermal exposure from contact with pets. Respiratory exposures were estimated for 7 population groups; adult males; adult females; children, age 1-2; children, age 3-5; children, age 6-8; males, age 9-11; and females, age 9-11. The corresponding exposures were 0.0015 mg/kg/day (MOE=33), 0.0013 mg/kg/day (MOE=38), 0.0037 mg/kg/day (MOE=14), 0.0033 mg/kg/day (MOE=15), 0.0027 mg/kg/day (MOE=19), 0.0026 mg/kg/day (MOE=19), and 0.0023 mg/kg/day (MOE=22). These MOEs are all of concern."

AMVAC Comments: AMVAC does not consider the use of weak data from a previous registrant as suitable for calculation of an MOE. A more robust proposal will be sent to the Agency.

Response: HED used the best available data for assessing the risks from flea collar uses, recognizing the limitations of that data set. The Agency is looking forward to receiving a more robust data set or analysis from the registrant. This is a technical issue that will be addressed at a future date, pending the submission of more information from the registrant.

p44,#4,L1:

The risk assessment states: "The assessment was obtained by using dislodgeable foliar residue information from a study found in the scientific literature and a registrant submitted study measuring the exposures of individuals performing defined activities on carpets following the activation of a total release fogger (Jaquith 1998h). The dislodgeable foliar residue study indicated that residues declined rapidly, resulting in a short term exposure scenario; therefore, the NOEL of 0.5 mg/kg/day from an acute human study was used for risk assessment. An MOE of 30 is required. Inhalation exposure was considered to be negligible due to rapid dissipation of DDVP under these conditions. Since lawn care products are intended to be used in a residential/park setting, an exposure interval of 3 hours was used for this assessment. This approximates the amount of time required for drying of the spray, which is a label requirement before reentry in some cases.

AMVAC Comments: Amvac notes that there are three recent dislodgeable residue studies available to the Agency which it believes should be used for calculation of the MOE.

Response: HED recognizes that there have been studies measuring dislodgeable residues of DDVP on turf. These studies are currently undergoing review. If acceptable, they will be used to revise the risk assessment for turf/recreational uses.

58. **p44,#4,L5.**

The risk assessment states: The assessment for flea collar exposure was derived from a study submitted by a previous registrant. There were a number of technical problems with that study and it is considered a weak data set (Jaquith 1987) . The inhalation NOEL of 0.05 mg/kg/day from a chronic rat study was used for inhalation risk assessment. An MOE of 300 is required. It was assumed that an individual spends 1 hour per day in close proximity to an animal wearing a flea collar and 8 hours per day in the general area (Jaquith 1998d). There are no data with which to estimate dermal exposure from contact with pets.

AMVAC Comments: The reference should be Jaquith 1998c, not 1998d.

Response: The reference should be Jaquith 1998c (March 18, 1998) instead of Jaquith 1998d. HED notes that this assessment has been revised to include comments from the HED EXPOSAC (7).

59. **Table 16/f2:**

The risk assessment states: An average resident applicator weighs 70 kg and has a respiratory volume of 1.5 m^3 /hour (PHED default value). No protection from clothing is assumed.

AMVAC Comments: The breathing rate of 1.5 m^3/hr is the PHED default, however this is applicable to outdoor workers involved in moderate activities. The recommended EPA breathing rate for residential moderate activities is 1.2 m^3/hr (EPA, Exposure Factors Handbook, August 1996, Tables 5-23, page 5-22).

Response: HED used the default value from PHED because the assessment was derived from that data source for aerosol spray can

applications. A change from 1.5 to 1.2 m³/hr would result in minimal changes in the risk assessment. The default value from PHED was selected to assure consistency with other PHED-derived estimates of exposure. At any rate, if the aerosol spray can formulations are no longer available to the homeowner population, this becomes a moot point and the risk assessments for homeowners would not be derived from PHED but would address reentry exposures only.

60. **Table 6/f11:**

The risk assessment states: "An average mushroom house has a volume of 30,000 ft^3. Dichlorvos is applied at a rate of 3.0 grams of active ingredient per 1000 ft^3 or 90 grams per treatment; 16 days per year, 10 houses per day; 4 minutes per house or 40 minutes per day. Protective clothing was slightly different for each application method. For reentry exposure, assumed that a worker reenters a ventilated mushroom house 24 hours after treatment and is exposed for 8 hours."

AMVAC Comments: The maximum use rate of DDVP for this use on the proposed label is 2.0 not 3.0 g ai/1000 ft³.

Response: The proposed label does restrict the application rate of DDVP to mushroom houses at a level of 2 g ai per 1000 ft³. However, the fogging applications have been deleted by the registrants recent proposal (Appendix A). The exposure assessment was based on limited data from a study conducted by the California Department of Food and Agriculture (now CALEPA). The material was applied at a rate of 34 grams per 16000 ft³ (2.1 g/1000 ft³), reasonably close to that proposed by the technical label. The existing exposure assessment provides the best estimate of the exposure that would occur for workers reentering mushroom houses treated with this material.

63. **p55,#3,L5:**

The risk assessment states: "Outstanding exposure data requirements exist for turf and greenhouse uses. For turf, both application and postapplication data are required. For the greenhouse use, postapplication data are required. The DDVP Registrant is a member of both the Agricultural Re-entry Task Force (ARTF) and the Outdoor Residential Exposure Task Force (ORETF). These data have been called in under the generic Data Call Ins (DCIs) for Turf and Agriculture. The following guideline studies are required:

GDLN 875.2100 Foliar Residue Dissipation Study (replaces GDLN 132-1(a))

GDLN 875.1100 Dermal Exposure - Outdoor Use (replaces GDLN 133-3)

GDLN 875.1200 Dermal Exposure - Indoor Use (replaces GDLN 133-3)

GDLN 875.1300 Inhalation Exposure - Outdoor (replaces GDLNs 133-4)

GDLN 875.1400 Inhalation Exposure - Indoor (replaces GDLN 133-4)

GDLN 875.2400 Dermal Exposure (replaces GDLN 133-3, Dermal Passive Dosimetry)

GDLN 875.2500 Inhalation Exposure (replaces GDLN 133-4, Inhalation Passive Dosimetry)

AMVAC Comments: No Data Call-In (DCI) has been issued for GDLN 875.1200 or GDLN 875.1400. However, Amvac has already submitted DDVP-specific data measuring indoor residential (MRID No. 41928801) and indoor commercial (MRID 42768701).

Response: The studies submitted by Amvac for indoor residential and indoor commercial exposures have been evaluated by the Agency and included in the risk assessment. There are no studies directly monitoring the dermal or respiratory exposures of individuals in the outdoor environment. In order to address the outdoor residential exposure scenario it was necessary for the Agency to use a combination of the indoor study and literature data to address this issue. These provide the Agency's best estimates of the exposures of individuals in the residential outdoor/recreational environment at this time.

64. **p55,#5,L1**

The risk assessment states: The Agency has recently received two foliar dissipation studies from the Registrant. These two studies are under review, and will be incorporated into the risk assessment upon completion of the Agency's review.

AMVAC Comments: Three FDR studies are available.

Response: The studies submitted by Amvac are currently under review and, if acceptable will be used to revise the risk assessment where appropriate.

REFERENCES

1) Memorandum from C. Scheltema (RCAB) to D. Utterback (SRRD) titled "Preliminary Risk Assessment for Dichlorvos", dated December 3, 1998.

2) Label for DDVP Technical Grade. EPA Reg. No. 5481-96, Accepted August 1, 1996.

3) Facsimile Transmission from A. Manley (AMVAC) to J. Leahy (RD) titled "DDVP Technical Label and Maximum Use Rate Table", dated September 18, 1998.

4) Memorandum from D. Jaquith (CEB2) to C. Scheltema (RCAB) titled "Revised Applicator Exposures to DDVP Resulting from Crack and Crevice Use and the Use of Aerosol Products (PC Code 084001, Barcode D246130), dated June 24, 1998.

5) Memorandum from M. Dow (BUD) to D. Pilitt (RD) titled "DDVP (Vapona) QUA", dated October 2, 1985.

6) Memorandum from D. Jaquith (OREB) to B. Lowery (SRRD) titled "Review of Exposure Monitoring Study for Use of DDVP in Food Processing Establishments", dated December 6, 1993.

7) Jaquith D. (1998). Response to Comments from EXPOSAC on Exposure Assessment for Dichlorvos (DDVP) from Flea Collars. November 6, 1998.

APPENDIX A

AMVAC CHEMICAL CORPORATION ™
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Date: 19 August 1998

SUBJECT: VOLUNTARY DELETIONS OF USES ON THE DDVP TECHNICAL LABEL

Dear Dennis,

AMVAC is voluntarily deleting the following uses from the DDVP technical label:-

Hand-Held Fogger use ✓

Outdoor Fogger use ✓

Dry Bait Formulation use around Homes, Cabins and Residential Lawns ✓

Food Service Establishments (excluding non-food/feed servicing areas): restaurants, cafeterias, taverns, delicatessens, mess halls, school and institutional dining areas, hospitals, mobile canteens, vending machines, groceries and markets.

If you require any further information then please give me a call on (323)526-2384.

Regards,

Ann Manley

Director of Toxicology

Cc Eric Wintemute
David Cassidy
Bill Feiler
Ian Chart
Jon Wood
Bob Gilbane

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APPENDIX A